April 1, 2002

The Honorable Christine Todd Whitman Administrator U.S. Environmental Protection Agency Ariel Rios Building Room 3000, #1101-A 1200 Pennsylvania Ave., N.W. Washington, DC 20460

Subject: Comments on the ACC's HPV Test Plan for the Alkaryl Sulfonates

Dear Administrator Whitman:

The following comments on the American Chemistry Council's (ACC's) test plan for the alkaryl sulfonates category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The ACC test plan for alkaryl sulfonates reflects a more thoughtful approach to the development of robust summaries and test plans for lubricant additives. The information is complete and well presented. The ACC has incorporated a large number of chemicals into a scientifically justifiable category and intends to draw on existing data to reduce testing. However, the ACC has proposed four limit tests for acute toxicity to fish (with no mention made of the use of the *in vitro* Tetratox or Ecosar), one repeat dose toxicity test, and one reproductive toxicity test. The ACC should expand its analysis to include information on related chemicals and withdraw its proposals for any tests on animals.

Although the ACC presents a well-developed test plan, it does not comply with the following terms of the October 1999 Agreement among industry, the EPA, health organizations, animal protection organizations, and environmental groups:

- 1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.
- 2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.

3. Participants shall maximize the use of scientifically appropriate categories of related chemicals and structure activity relationships.

The alkaryl sulfonates are generally used as lubricant additives. The category members are discrete chemicals with incremental changes and the same functional groups, thereby satisfying the criteria described in the EPA guidance document. The category includes different sulfonic acids and sulfonic acid salts used as additives to finished lubricants whose functional groups, physical properties, and chemical properties are all similar. (See EPA's Draft Guidance on Developing Robust Summaries, October 22, 1999. Viewable at http://www.epa.gov/chemrtk/robsumgd.htm)

However, the ACC should have included a number of additional compounds in the alkaryl sulfonates category. Importantly, many of the overlooked substances are individual compounds, so that their chemistry and toxicology is better understood than that of complex mixtures. Additionally, many of these other substances already have a significant body of data associated with them that would provide additional insight into the toxicology of the compounds in this category, further reduce animal testing, and expand our knowledge and understanding of these compounds.

Table 1 specifically lists a small group of the compounds that could be included in this category. While the proposed test plan dismisses the inclusion of lighter alkaryl compounds (page 4), the inclusion of C10-C14 compounds would provide a logical continuum of information of the toxicity of these compounds. Also, because of the higher solubility of these lighter compounds, they have the potential to be more bioavailable, and thus the toxicity of these lighter compounds could reasonably be viewed as an upper bound to alkaryl compound toxicity. Because many of these lighter compounds are used in consumer products, a greater database of information is available on them, providing insight into the category as a whole. The abundant evidence suggests that these chemicals generally exhibit low toxicity. As it states in the cover letter of the ACC test plan, no adverse effects are expected from these compounds.

Once again, this test plan shows that inter-industry cooperation is not being emphasized in the development of test plans. The narrow group of lubricant additives in this test plan could be greatly expanded to include surfactants used in other areas. We again request that the EPA inform us how it plans to encourage inter-industry cooperation in test plans.

Overall, the ACC's test plan represents a step in a productive direction towards the application of thoughtful toxicology. However, the test plan still proposes much unnecessary fish and mammalian testing. It should be improved by drawing on the extensive database on structurally similar compounds and by expanding the category.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016. I can also be reached via e-mail at neardello@perm.org.

Sincerely,

Nicole Cardello, M.H.S. Staff Scientist

Table 1. Potential Additions to the Alkaryl Sulfonate Category

## **CAS Number Substance**

25155300	Benzenesulfonic acid, dodecyl-, sodium salt
25496019	Benzenesulfonic acid, tridecyl-
25619561	Naphthalenesulfonic acid, dinonyl-, barium salt
26248248	Benzenesulfonic acid, tridecyl-, sodium salt
26264051	Benzenesulfonic acid, dodecyl-, compd. with isopropylamine (1:1)
26264062	Benzenesulfonic acid, dodecyl-, calcium salt
27176870	Benzenesulfonic acid, dodecyl-
27177771	Benzenesulfonic acid, dodecyl-, potassium salt
28519020	Benzenesulfonic acid, dodecyloxydi-, disodium salt
61789853	Sulfonic acids, petroleum
68081812	Benzenesulfonic acid, mono-C10-16-alkyl derivs., sodium salts
68411325	Benzenesulfonic acid, dodecyl-, branched
68439576	Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts
68439576	Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts
68584225	Benzenesulfonic acid, C10-16-alkyl derivs.
68608888	Benzenesulfonic acid, mono-C11-13-branched alkyl derivs.
68608899	Benzenesulfonic acid, mono-C11-13-branched alkyl derivs., sodium salts
68783960	Sulfonic acids, petroleum, calcium salts, overbased
68953968	Benzenesulfonic acid, mono-C11-13-branched alkyl derivs., calcium salts
70024678	Benzenesulfonic acid, C16-24-alkyl derivs.
70775949	Sulfonic acids, C10-18-alkane, pH esters